

**REMARKS**

Claims 35-46 are pending in this application. The specification has been amended to include a paragraph indicating the priority information as requested by the Examiner. Accompanying this response, applicants also submit a newly executed declaration and an Application Data Sheet. No new matter has been added.

The issues outstanding in this application are as follows:

- The Specification has been objected to as allegedly containing informalities in that a paragraph indicating the priority claim is lacking.
- Claims 35, 37-41 and 45-46 have been rejected by the Examiner under 35 U.S.C. § 103(a) as being allegedly being unpatentable over Belfrage et al. (Immunology, 10:183, 1997).
- Claims 35, 37-38, 41 and 45-46 have been rejected by the Examiner under 35 U.S.C. § 102(b) as being allegedly being anticipated by Lando et al., (J. Immunol., 157:2857, 1996).
- Claims 35 and 37-46 have been rejected by the Examiner under 35 U.S.C. § 103(a) as being allegedly being unpatentable over Belfrage et al. in view of Abrahmsen et al. (WO 96/01650) and Antonsson et al. (U.S. 6,514,498).
- Claims 35, 37-41 and 45-46 have been rejected by the Examiner under 35 U.S.C. § 103(a) as being allegedly being unpatentable over Belfrage et al. (Thesis, 1996)
- Claims 35 and 37-46 have been rejected by the Examiner under 35 U.S.C. § 103(a) as being allegedly being unpatentable over Belfrage et al. (Thesis, 1996) in view of Abrahmsen et al. (WO 96/01650) and Antonsson et al. (U.S. 6,514,498).

Applicants respectfully traverse the outstanding rejections and objections, and Applicants respectfully request reconsideration and withdrawal thereof in light of the amendments and remarks contained herein.

**I. The Priority claim is included in the Specification.**

The Office has indicated that the Specification has been objected to as allegedly containing informalities by lacking a paragraph indicating the claim for priority. Applicants respectfully traverse.

Applicants have added a paragraph as requested by the Examiner to indicate the priority of this application. Thus, without acquiescence, Applicants respectfully request that the objection be withdrawn.

**II. Claims 35, 37-41 and 45-46 are not obvious under 35 U.S.C. § 103(a).**

Claims 35, 37-41 and 45-46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Belfrage et al. The Action states that Belfrage et al. teaches coadministration of a wild type superantigen conjugated to a targeting antibody and using IL-2 to increase the immunotherapeutic killing of cancer cells. Applicants traverse and respectfully request withdrawal of the Belfrage et al. reference.

Applicants assert that they are the authors of the Belfrage et al. reference cited against the present invention. Applicants submit a Declaration by Terje Kalland (paragraphs 4 and 6), which states that the Belfrage et al. reference describes applicants' work. Thus, in light of the Declaration by Terje Kalland, Applicants have provided sufficient evidence to remove Belfrage et al. as a reference, and respectfully request that the rejection be withdrawn. *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA).

**III. Claims 35, 37-38, 41 and 45-46 are not anticipated under 35 U.S.C. § 102(b).**

Claims 35, 37-38, 41 and 45-46 were rejected under 35 U.S.C. § 102(b) as being anticipated by Lando et al. The Action states that Lando et al. teaches coadministration of a superantigen conjugated to a targeting antibody and of IL-2 in a culture system in which the target cells express a tumor antigen. Applicants traverse and respectfully request withdrawal of the Lando et al. reference.

Applicants assert that they are the authors of the Lando et al. reference cited against the present invention. Applicants submit a Declaration by Terje Kalland (paragraphs 5 and 6), which states that the Lando et al. reference describes applicants' work. Thus, in light of the Declaration by Terje Kalland, Applicants have provided sufficient evidence to remove Lando et al. as a reference, and respectfully request that the rejection be withdrawn. *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA).

**IV. Claims 35 and 37-46 are not obvious under 35 U.S.C. § 103(a).**

Claims 35, and 37-46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Belfrage et al. in view of Abrahmsen et al. (WO 96/01650) and Antonsson et al. (U.S. 6,514,498). The Action states that it would have been obvious to employ the targeted superantigens that were modified and taught by Abrahmsen et al. and Antonsson et al. in view of Belfrage. Applicants traverse and respectfully request withdrawal of the Belfrage et al.

Applicants assert that sufficient evidence has been provided in the 1132 Declaration, which is provided herein, to remove Belfrage et al. as a reference. In light of the removal of the primary reference, applicants discuss the remaining two references.

Obviousness can only be established by combining or modifying the references of the prior art to produce the claimed invention when there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Applicants assert that Abrahmsen (WO 96/01650) and Antonsson et al. (U.S. 6,514,498) only teach a conjugate of a superantigen and a targeting moiety, such as an antibody. Neither Abrahmsen nor Antonsson teach or suggest using cytokines to enhance the immunotherapeutic effectiveness of the superantigen conjugate. Thus Abrahmsen and

Antonsson alone or in combination do not teach or suggest all the elements of the present invention. Therefore, applicants respectfully request withdrawal of the § 103(a) obviousness rejection.

**V. Claims 35, 37-41 and 45-46 are not obvious under 35 U.S.C. § 103(a).**

Claims 35, 37-41 and 45-46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Belfrage et al. (Thesis, 1996). The Action states Belfrage teaches the co-treatment of tumors with SEA and with IL-2. Specifically, the Action states that the Belfrage Thesis suggests a strategy of enhancing T-cell activity against tumors while limiting the superinduction of cytokines to only the tumor area, by virtue of employing IL-2 and a monoclonal antibody-SEA fusion protein. Applicants traverse.

Applicants assert that they are the authors of the Belfrage Thesis cited against the present invention. Applicants submit a Declaration by Morten Soegard, Lars Abrahmsen, Peter Lando, Göran Forsberg, Terje Kalland, Mickael Dohlsten and Hans Belfrage (paragraphs 1-6), which states that the Belfrage Thesis describes applicants' work. Thus, in light of the Declaration, Applicants have provided sufficient evidence to remove Belfrage Thesis as a reference, and respectfully request that the rejection be withdrawn. *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA).

In view of the above arguments and the Declaration, applicants respectfully request withdrawal of the § 103(a) obviousness rejection.

**VI. Claims 35, and 37-46 are not obvious under 35 U.S.C. § 103(a).**

Claims 35, and 37-46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Belfrage et al. (Thesis, 1996) in view of Abrahmsen et al. (WO 96/01650) and Antonsson et al. (U.S. 6,514,498). The Action states that it would have been obvious to employ the targeted superantigens that were modified and taught by Abrahmsen et al. and Antonsson et al. in view of Belfrage. Applicants traverse.

Applicants assert that sufficient evidence has been provided in the 1.32 Declaration, which is provided herein, to remove Belfrage Thesis as a reference. In light of the removal of the primary reference, applicants discuss the remaining two references.

Obviousness can only be established by combining or modifying the references of the prior art to produce the claimed invention when there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Applicants assert that Abrahmsen (WO 96/01650) and Antonsson et al. (U.S. 6,514,498) only teach a conjugate of a superantigen and a targeting moiety, such as an antibody. Neither Abrahmsen nor Antonsson teach or suggest using cytokines to enhance the immunotherapeutic effectiveness of the superantigen conjugate. Thus, Abrahmsen and Antonsson alone or in combination do not teach or suggest all the elements of the present invention. Therefore, applicants respectfully request withdrawal of the § 10 (a) obviousness rejection.

### CONCLUSION

Claims 35-46 are now pending in this application. Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. 10001907 from which the undersigned is authorized to draw

If there are any outstanding issues, the Examiner is requested to contact the undersigned for quick resolution.

Dated: August 4, 2003

Respectfully submitted,

By 

Melissa W. Acosta

Registration No.: 45, 872

FULBRIGHT & JAWORSKI, L.P.

1301 McKinney, Suite 5100

Houston, Texas 77010-3095

(713) 651-5407

(713) 651-5246 (Fax)